DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 8 - 2004

Ms. Elizabeth Platt
Regulatory Affairs Manager/Quality Assurance
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, CA 92618-1200

Re: k042335
Trade/Device Name: Architect Free PSA MasterCheck
Architect Total PSA MasterCheck
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class II
Product Code: JJY
Dated: August 26, 2004
Received: August 30, 2004

Dear Ms Platt:

This letter corrects our substantially equivalent letter of September 17, 2004 regarding the Architect Free PSA MasterCheck and Architect Total PSA MasterCheck in which the Architect Total PSA MasterCheck was omitted from the listing of the trade name(s).

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Robert L. Becker, Jr., M,D,. PhD
DIRECTOR
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042335

Device Name: **Architect Free PSA MasterCheck**

Indications For Use: **Free PSA MasterCheck is intended for use in the verification of sensitivity, calibration linearity and reportable range of the Free PSA assay on the Abbott ARCHITECT i System.**

Device Name: **Architect Total PSA MasterCheck**

Indications For Use: **Total PSA MasterCheck is intended for use in the verification of sensitivity, calibration linearity and reportable range of the Total PSA assay on the Abbott ARCHITECT i System.**

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K042335

SEP 17 2004

K042335

Summary of Safety and Effectiveness

Architect MasterCheck Controls (PSA and PSA Free)

1.0 Submitter

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Contact Person

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Regulatory Affairs Specialist
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Date of Summary Preparation

August 26, 2004

2.0 Device Identification

Product Name:

- ❑ Architect Free PSA MasterCheck
- ❑ Architect PSA MasterCheck

Common Name:	Multi-analyte Controls, (Assayed and unassayed)
Classifications:	Class I
Product Code:	JJY
Regulation Number:	21 CFR 864.1660

3.0 Device to Which Substantial Equivalence is Claimed

Architect Progesterone MasterCheck
Abbott Laboratories
Abbott Park, IL 60064

510 (k) Number: K990393

4.0 Description of Device

These are liquid products prepared from HEPES buffer with protein (bovine), constituents of human origin, stabilizers and preservatives. (Level 0 does not contain preservatives or constituents of human origin).

5.0 Intended Use

Architect MasteChecks are intended for use in the verification of sensitivity, calibration linearity and reportable range of the Free PSA or Total PSA assay on the Abbott ARCHITECT ¡ System.

6.0 Preservatives:

Architect MasteChecks do not contain sodium azide as a preservative. They contains a broad-spectrum anti-microbial cocktail as a preservative where the concentration of any one ingredient is less than 0.1%. At this low level, these ingredients are not expected to cause a health hazard to the user. And thus, domestic and international regulations do not require this type of information on the vial or box label.

7.0 Comparison of the new device with the Predicate Device

The new Architect MasterCheck products claim substantial equivalence to the Architect Progesterone MasterCheck currently in commercial distribution (K990393). The new Architect MasterCheck products contain either Free PSA or Total PSA analyte.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Laboratories Architect Free PSA MasterCheck Architect PSA MasterCheck (New Device)		Abbott Laboratories Architect Progesterone MasterCheck (Predicate Device K990393)
Similarities			
Intended Use	Free PSA MasteCheck is intended for use in the verification of sensitivity, calibration linearity and reportable range of the Free PSA assay on the Abbott ARCHITECT *i System*	Total PSA MasteCheck is intended for use in the verification of sensitivity, calibration linearity and reportable range of the total PSA assay on the Abbott ARCHITECT *i System.*	Progesterone MasteCheck is intended for use in the verification of sensitivity, calibration linearity and reportable range of the Progesterone assay on the Abbott ARCHITECT *i System.*
Form	Liquid		Liquid
Open Vial	3 days at 2°C to 8°C		3 days at 2°C to 8°C
Storage Stability (Unopened)	2°C to 8°C Until expiration date		2°C to 8°C Until expiration date
Differences			
Matrix	HEPES buffer with protein (bovine)		Human Serum
Analytes	Contains the following analyte: • Free PSA (Architect Free PSA MasterCheck) • Total PSA (Architect Total PSA MasterCheck)		Contains the following analyte: • Progesterone

1.0 STATEMENT OF SUPPORTING DATA

Stability studies have been performed to determine the open vial stability and shelf life for these products. Product claims are as follows:

- Open vial Stability: 3 days when stored tightly capped at 2 to 8°C.
- Shelf Life: Twelve months when stored at 2 to 8 °C

All supporting data is retained on file at Bio-Rad Laboratories.